IN THE UNITED STATES DISTRICT COURT FOR THE SOUTHERN DISTRICT OF TEXAS HOUSTON DIVISION

UNITED STATES OF AMERICA,

Plaintiff,

v.

Civil Action No. 4:19-cv-3214

TOPWAY ENTERPRISES, INC, a corporation, d/b/a KAZY'S GOURMET, and JEFF LIAO, YING CHEN, and ADWIN LIAO, individually,

Defendants.

PLAINTIFF UNITED STATES OF AMERICA'S COMPLAINT FOR PERMANENT INJUNCTION

1. The United States of America brings this action against Topway Enterprises, Inc., a corporation d/b/a Kazy's Gourmet, and Jeff Liao, Ying Chen, and Adwin Liao individually (collectively, Defendants), under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 332(a), and the inherent equitable authority of this Court, to permanently enjoin and restrain Defendants from violating: (A) 21 U.S.C. § 331(a), by introducing or delivering for introduction, or causing to be introduced or delivered for introduction, into interstate commerce articles of food, within the meaning of 21 U.S.C. § 321(f), that are adulterated within the meaning of 21 U.S.C. § 342(a)(4) in that they have been prepared, packed or held under insanitary conditions whereby they may have been rendered injurious to health; and (B) 21 U.S.C. § 331(k), by causing articles of food within the meaning of 21 U.S.C. § 321(f) to become adulterated within the meaning of 21 U.S.C. § 342(a)(4), in that they have been prepared, packed, or held under insanitary conditions whereby they may have been rendered injurious to health, while held for sale after shipment of one or more components in interstate commerce.

JURISDICTION AND VENUE

- 2. This Court has jurisdiction over the subject matter and over all parties to this action under 28 U.S.C. §§ 1331 and 1345, 21 U.S.C. § 332, and its inherent equitable authority. The Court has jurisdiction over the defendants because the corporation, Topway Enterprises, Inc., has its principal place of business in Houston, Texas, and the individual defendants work at the corporation's location, which is located in this district.
 - 3. Venue in this District is proper pursuant to 28 U.S.C. § 1391(b) and (c).

PARTIES

- 4. Plaintiff is the United States of America.
- 5. Defendant Topway Enterprises, Inc. ("Topway") is a Texas corporation doing business as Kazy's Gourmet, with its principal place of business at 4001 Briarpark Drive, Houston, Texas ("Defendants' facility"), within the jurisdiction of this Court.
- 6. Defendant Jeff Liao is the President and co-owner of Topway. He has overall responsibility for Topway's operations. He performs his duties at Defendants' facility, within the jurisdiction of this Court.
- 7. Defendant Ying (Linda) Chen, Mr. Jeff Liao's wife, is co-owner of Topway. During a February 2019 inspection by the Food and Drug Administration ("FDA"), Ms. Chen identified herself as the most responsible person at the facility. Defendant Chen performs her duties at Defendants' facility, within the jurisdiction of this Court.
- 8. Defendant Adwin Liao is the son of Defendants Jeff Liao and Ying Chen, and the manager of Defendants' facility. He accompanied FDA on the February 2019 inspection, and attended a Regulatory Meeting with FDA in March 2019, as the Topway representative. Defendant Adwin Liao performs his duties at Defendants' facility, within the jurisdiction of this Court.
 - 9. Defendants receive, process, prepare, pack, hold, and distribute articles of food,

within the meaning of 21 U.S.C. § 321(f), including, but not limited to, ready-to-eat fish and fishery products.

10. Defendants' ready-to-eat fish and fishery products are made from ingredients that have been shipped in interstate commerce. Defendants deliver their ready-to-eat fish and fishery products to customers located outside the state of Texas. For example, Defendants receive fish and fishery products from North Carolina, and ship ready-to-eat fish and fishery products for sushi to restaurants located outside of Texas, including to restaurants in Louisiana, Alabama, and Mississippi.

DEFENDANTS' VIOLATIONS

- 11. Defendants violate 21 U.S.C. § 331(a) by introducing or delivering for introduction, or causing to be introduced or delivered for introduction, into interstate commerce articles of food that are adulterated within the meaning of 21 U.S.C. § 342(a)(4).
- 12. Defendants violate 21 U.S.C. § 331(k) by causing articles of food to become adulterated within the meaning of 21 U.S.C. § 342(a)(4), while held for sale after shipment of one or more components in interstate commerce.
- 13. Defendants' food is adulterated within the meaning of 21 U.S.C. § 342(a)(4) in that it has been prepared, packed or held under insanitary conditions whereby it may have been rendered injurious to health. The insanitary conditions include, but are not limited to, the widespread presence of *Listeria* at Defendants' facility.

- 14. *Listeria monocytogenes* is a pathogenic organism that has a reasonable probability of causing serious adverse health consequences or death to humans.
- 15. FDA conducted an inspection of Defendants' facility from February 4-8, 2019, during which FDA observed insanitary conditions and poor employee production practices.
- 16. Approximately 58% of the samples collected by FDA during the February 2019 inspection tested positive for non-pathogenic species of *Listeria*, which are considered indicator organisms, meaning that they provide evidence that *Listeria monocytogenes*, a pathogenic organism, could survive under similar physical, chemical, and nutrient conditions.
- 17. On June 24-July 3, 2019, under contract with FDA, the Texas Department of State Health Services ("TX DSHS") conducted a follow-up inspection of Defendants' facility and observed continuing insanitary conditions and poor employee production practices.
- 18. Approximately 65% of the samples collected during the June/July 2019 inspection tested positive for *Listeria*, including four that revealed pathogenic *Listeria monocytogenes*.
- 19. On July 3, 2019, in response to the June-July 2019, inspection, Defendants temporarily ceased operations at their facility, but did not inform FDA that they were operating in a temporary location, taking utensils, aprons, and small equipment with them.
- 20. On July 10, 2019, Defendants resumed operations at their facility—and refused to cease such operations—despite hearing from FDA experts on July 11, 2019 that adequate corrective action had not been implemented and the ready-to-eat seafood processed at their facility was likely to be contaminated with *L. monocytogenes* and could cause serious adverse health consequences or death to humans.
- 21. On July 17, 2019, FDA suspended Defendants' facility's registration under 21 U.S.C. § 350d(b), based on FDA's determination that food manufactured, processed, packed,

received, and/or held at Defendants' facility had a reasonable probability of causing serious adverse health consequences or death to humans.

22. In response to the registration suspension, Defendants have taken certain corrective action, including presenting FDA with a Corrective Action Plan. That plan, while promising, is not sufficient to alleviate FDA's concern that ready-to-eat food processed at Defendant's facility is likely to be contaminated with *Listeria*, absent the intervention of the Court. As of the date of this complaint, Defendants' facility registration remains suspended.

WHEREFORE, Plaintiff respectfully requests that this Court:

- I. Permanently restrain and enjoin, under 21 U.S.C. § 332(a), Defendants and each and all of their officers, agents, employees, representatives, successors, assigns, attorneys, and any and all persons in active concert or participation with any of them (including individuals, directors, corporations, subsidiaries, affiliates, partnerships, and "doing business as" entities), who receive notice of the Court's order from, directly or indirectly:
- A. violating 21 U.S.C. § 331(a), by introducing, delivering, and causing the introduction and delivery for introduction into interstate commerce of any article of food that is adulterated within the meaning of 21 U.S.C. § 342(a)(4); and
- B. violating 21 U.S.C. § 331(k), by doing and causing to be done any act that causes any article of food to become adulterated within the meaning of 21 U.S.C. § 342(a)(4), while such article is held for sale after shipment of one or more of its components in interstate commerce;
- II. Order Defendants and each and all of their officers, agents, employees, representatives, successors, assigns, attorneys, and any and all persons in active concert or participation with any of them (including individuals, directors, corporations, subsidiaries, affiliates, partnerships, and "doing business as" entities), who receive notice of the Court's order to

5

cease, directly or indirectly, receiving, processing, manufacturing, preparing, packaging, holding, and distributing any article of food within the meaning of 21 U.S.C. § 321(f), at or from Defendants' facility (and any other or new location at or from which Defendants receive, process, manufacture, prepare, pack, hold, or distribute food), unless and until Defendants bring their operations into compliance with the Act and its implementing regulations to the satisfaction of FDA; and

III. Award the United States its costs herein, including the costs of investigation to date, and such other relief as the Court may deem just and proper.

Respectfully submitted,

Of Counsel:

ROBERT P. CHARROW
General Counsel
United States Department of Health
and Human Services

STACY CLINE AMIN
Chief Counsel
Food and Drug Administration
Deputy General Counsel
United States Department of Health
and Human Services

ANNAMARIE KEMPIC Deputy Chief Counsel, Litigation Food and Drug Administration

BARBARA ALKALAY Senior Counsel Office of the General Counsel Food and Drug Division 10903 New Hampshire Avenue White Oak 32, Room 4442 Silver Spring, MD 20993-0002 Telephone: (301) 348-3085 Barbara.Alkalay@fda.hhs.gov RYAN K. PATRICK United States Attorney Southern District of Texas

By: <u>s/</u>_

Andrew A. Bobb Assistant United States Attorney SBOT No. 02530350 Fed. Bar No. 9041 1000 Louisiana, Suite #2300 Houston, Texas 77002

Tel: (713) 567-9766 Fax: (713) 718-3303

Email: Andrew.Bobb@usdoj.gov

JOSEPH H. HUNT Assistant Attorney General Civil Division

DAVID M. MORRELL Deputy Assistant Attorney General

GUSTAV W. EYLER

Director

Joshua D. Rothman

Trial Attorney

State Bar Number 108272014 (New Jersey)

Consumer Protection Branch U.S. Department of Justice 450 5th Street NW, Suite 6400S

Washington, D.C. 20001 Telephone: 202-514-1586

Fax: 202-514-8742

Joshua.D.Rothman@usdoj.gov

Attorneys in Charge for the United States

JS 44 (Rev. 02/19)

CIVIL COVER SHEET

The JS 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. (SEE INSTRUCTIONS ON NEXT PAGE OF THIS FORM.)

		 ·					
I. (a) PLAINTIFFS				DEFENDANTS			
United States of America				Topway Enterprises, Inc., d/b/a Kazy's Gourmet; Jeff Liao, Ying Chen; Adwin Liao			
(b) County of Residence of First Listed Plaintiff				County of Residence of First Listed Defendant			
(EXCEPT IN U.S. PLAINTIFF CASES)				(IN U.S. PLAINTIFF CASES ONLY)			
(DICELLIN U.S. LEMINTEL CROES)				NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT OF LAND INVOLVED.			
(c) Attorneys (Firm Name, Address, and Telephone Number)				Attorneys (If Known)			
Joshua D. Rothman, Consumer Protection Branch, U.S. Department							
Justice, 450 5th Street N	W, Washington DC 20	0001, 202-514-1586	5	Road, Suite 1510,	Houston TX 77024, 84	4-824-2224	
II. BASIS OF JURISDICTION (Place an "X" in One Box Only)				. CITIZENSHIP OF PRINCIPAL PARTIES (Place an "X" in One Box for Plaintiff (For Diversity Cases Only) and One Box for Defendant)			
≯1 U.S. Government	3 Federal Question				rf def	PTF DEF	
Plaintiff	(U.S. Government)	Not a Party)	Citize		1		
					of Business Ir	1 This State	
2 U.S. Government		ip of Parties in Item III)	Citize	en of Another State	2	d Principal Place	
				en or Subject of a reign Country	3 🗇 3 Foreign Nation	□ 6 □ 6	
IV. NATURE OF SUIT	(Place an "X" in One Box Or	ıly)		Click here for: Nature	e of Suit Code Descriptions.		
CONTRACT	TO	ORTS	FC	DRFEITURE/PENALTY	BANKRUPTCY	OTHER STATUTES	
110 Insurance	PERSONAL INJURY	PERSONAL INJUR	Y 🗆 62	5 Drug Related Seizure	☐ 422 Appeal 28 USC 158	375 False Claims Act	
☐ 120 Marine ☐ 130 Miller Act	310 Airplane 315 Airplane Product	365 Personal Injury - Product Liability	J 60	of Property 21 USC 881 0 Other	☐ 423 Withdrawal 28 USC 157	376 Qui Tam (31 USC	
☐ 140 Negotiable Instrument	Liability	367 Health Care/	0	o Other	28 030 137	3729(a)) ☐ 400 State Reapportionment	
150 Recovery of Overpayment	🗇 320 Assault, Libel &	Pharmaceutical			PROPERTY RIGHTS	☐ 410 Antitrust	
& Enforcement of Judgment 151 Medicare Act	Slander 330 Federal Employers'	Personal Injury			820 Copyrights 830 Patent	430 Banks and Banking	
151 Medicare Act 152 Recovery of Defaulted	Liability	Product Liability 368 Asbestos Personal			350 Patent - Abbreviated	☐ 450 Commerce ☐ 460 Deportation	
Student Loans	☐ 340 Marine	Injury Product			New Drug Application		
(Excludes Veterans) 153 Recovery of Overpayment	345 Marine Product Liability	Liability PERSONAL PROPER	TV -	LABOR	☐ 840 Trademark	Corrupt Organizations	
of Veteran's Benefits	☐ 350 Motor Vehicle	370 Other Fraud		0 Fair Labor Standards	SOCIAL SECURITY 861 HIA (1395ff)	☐ 480 Consumer Credit ☐ 485 Telephone Consumer	
☐ 160 Stockholders' Suits	☐ 355 Motor Vehicle	371 Truth in Lending		Act	362 Black Lung (923)	Protection Act	
190 Other Contract	Product Liability	380 Other Personal	72	0 Labor/Management	863 DIWC/DIWW (405(g))		
195 Contract Product Liability 196 Franchise	360 Other Personal Injury	Property Damage 385 Property Damage	O 74	Relations 0 Railway Labor Act	☐ 864 SSID Title XVI ☐ 865 RSI (405(g))	☐ 850 Securities/Commodities/ Exchange	
	362 Personal Injury -	Product Liability		1 Family and Medical	((B))	■ 890 Other Statutory Actions	
REAL PROPERTY	Medical Malpractice	I anicoven pertury	70	Leave Act	PEDERAL TAY OTHER	□ 891 Agricultural Acts	
3 210 Land Condemnation	CIVIL RIGHTS ☐ 440 Other Civil Rights	PRISONER PETITION Habeas Corpus:		0 Other Labor Litigation 1 Employee Retirement	FEDERAL TAX SUITS 870 Taxes (U.S. Plaintiff	☐ 893 Environmental Matters ☐ 895 Freedom of Information	
220 Foreclosure	441 Voting	☐ 463 Alien Detainee	' '	Income Security Act	or Defendant)	Act	
230 Rent Lease & Ejectment	☐ 442 Employment	510 Motions to Vacate	:		☐ 871 IRS—Third Party	☐ 896 Arbitration	
☐ 240 Torts to Land☐ 245 Tort Product Liability	Accommodations	Sentence 530 General			26 USC 7609	☐ 899 Administrative Procedure Act/Review or Appeal of	
□ 290 All Other Real Property	☐ 445 Amer. w/Disabilities -			IMMIGRATION		Agency Decision	
• •	Employment	Other:		2 Naturalization Application		☐ 950 Constitutionality of	
	446 Amer. w/Disabilities - Other	☐ 540 Mandamus & Othe ☐ 550 Civil Rights	er 🔲 46	5 Other Immigration Actions		State Statutes	
	☐ 448 Education	555 Prison Condition		Actions			
		☐ 560 Civil Detainee -					
		Conditions of Confinement					
V. ORIGIN (Place an "X" in	0.7.011	Commonent					
X 1 Original □ 2 Rer	noved from 3	Remanded from Appellate Court	J 4 Rein Reop	ened Anothe	r District Litigation	on - Litigation -	
	Cita the U.S. Civil Ste	ituta undar tuhich vou ar	a filing (I	(specify)	Transfer	Direct File	
	21 Ü.S.C. § 331(a	a); 21 U.S.C. § 331	(k)	Oo not cite jurisdictional state	utes untess diversity).		
VI. CAUSE OF ACTION	Brief description of ca	iuse: ulterated food into i					
	introduction of ad	ulterated food into i	nterstate	e commerce			
VII. REQUESTED IN COMPLAINT: CHECK IF THIS IS A CLASS ACTION UNDER RULE 23, F.R.Cv.P.			D 1	DEMAND \$ CHECK YES only if demanded in complaint: JURY DEMAND:			
VIII. RELATED CASE	E(S)						
IF ANY	(See instructions):	JUDGE			DOCKET NUMBER _		
DATE 8 27	19	SIGNATURE OF A	ORNEY C	OF RECORD			
FOR OFFICE USE ONLY	-0.6 \$67	7	1	The second second second		Section 19 The Sectio	
RECEIPT # AN	MOUNT	APPLYING IF	J	JUDGE	MAG. JU	IDGE	

INSTRUCTIONS FOR ATTORNEYS COMPLETING CIVIL COVER SHEET FORM JS 44

Authority For Civil Cover Sheet

The JS 44 civil cover sheet and the information contained herein neither replaces nor supplements the filings and service of pleading or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. Consequently, a civil cover sheet is submitted to the Clerk of Court for each civil complaint filed. The attorney filing a case should complete the form as follows:

- **I.(a) Plaintiffs-Defendants.** Enter names (last, first, middle initial) of plaintiff and defendant. If the plaintiff or defendant is a government agency, use only the full name or standard abbreviations. If the plaintiff or defendant is an official within a government agency, identify first the agency and then the official, giving both name and title.
 - (b) County of Residence. For each civil case filed, except U.S. plaintiff cases, enter the name of the county where the first listed plaintiff resides at the time of filing. In U.S. plaintiff cases, enter the name of the county in which the first listed defendant resides at the time of filing. (NOTE: In land condemnation cases, the county of residence of the "defendant" is the location of the tract of land involved.)
 - (c) Attorneys. Enter the firm name, address, telephone number, and attorney of record. If there are several attorneys, list them on an attachment, noting in this section "(see attachment)".
- II. Jurisdiction. The basis of jurisdiction is set forth under Rule 8(a), F.R.Cv.P., which requires that jurisdictions be shown in pleadings. Place an "X" in one of the boxes. If there is more than one basis of jurisdiction, precedence is given in the order shown below.
 - United States plaintiff. (1) Jurisdiction based on 28 U.S.C. 1345 and 1348. Suits by agencies and officers of the United States are included here. United States defendant. (2) When the plaintiff is suing the United States, its officers or agencies, place an "X" in this box.
 - Federal question. (3) This refers to suits under 28 U.S.C. 1331, where jurisdiction arises under the Constitution of the United States, an amendment to the Constitution, an act of Congress or a treaty of the United States. In cases where the U.S. is a party, the U.S. plaintiff or defendant code takes precedence, and box 1 or 2 should be marked.
 - Diversity of citizenship. (4) This refers to suits under 28 U.S.C. 1332, where parties are citizens of different states. When Box 4 is checked, the citizenship of the different parties must be checked. (See Section III below; **NOTE: federal question actions take precedence over diversity cases.)**
- III. Residence (citizenship) of Principal Parties. This section of the JS 44 is to be completed if diversity of citizenship was indicated above. Mark this section for each principal party.
- IV. Nature of Suit. Place an "X" in the appropriate box. If there are multiple nature of suit codes associated with the case, pick the nature of suit code that is most applicable. Click here for: Nature of Suit Code Descriptions.
- V. Origin. Place an "X" in one of the seven boxes.
 - Original Proceedings. (1) Cases which originate in the United States district courts.
 - Removed from State Court. (2) Proceedings initiated in state courts may be removed to the district courts under Title 28 U.S.C., Section 1441.

 Remanded from Appellate Court. (3) Check this box for cases remanded to the district court for further action. Use the date of remand as the filing date
 - Reinstated or Reopened. (4) Check this box for cases reinstated or reopened in the district court. Use the reopening date as the filing date. Transferred from Another District. (5) For cases transferred under Title 28 U.S.C. Section 1404(a). Do not use this for within district transfers or multidistrict litigation transfers.
 - Multidistrict Litigation Transfer. (6) Check this box when a multidistrict case is transferred into the district under authority of Title 28 U.S.C. Section 1407.
 - Multidistrict Litigation Direct File. (8) Check this box when a multidistrict case is filed in the same district as the Master MDL docket. **PLEASE NOTE THAT THERE IS NOT AN ORIGIN CODE 7.** Origin Code 7 was used for historical records and is no longer relevant due to changes in statue.
- VI. Cause of Action. Report the civil statute directly related to the cause of action and give a brief description of the cause. **Do not cite jurisdictional statutes unless diversity.** Example: U.S. Civil Statute: 47 USC 553 Brief Description: Unauthorized reception of cable service
- VII. Requested in Complaint. Class Action. Place an "X" in this box if you are filing a class action under Rule 23, F.R.Cv.P.

 Demand. In this space enter the actual dollar amount being demanded or indicate other demand, such as a preliminary injunction.

 Jury Demand. Check the appropriate box to indicate whether or not a jury is being demanded.
- VIII. Related Cases. This section of the JS 44 is used to reference related pending cases, if any. If there are related pending cases, insert the docket numbers and the corresponding judge names for such cases.

Date and Attorney Signature. Date and sign the civil cover sheet.